

## REMARKS

The present invention relates to processes for manufacturing opiates. In particular, the present invention relates to a process for manufacturing opiates such as codeine by converting a morphine component into codeine. Claims 1-14 have been cancelled, claim 17 has been amended, and new claims 31 to 35 have been added.

### Rejection of Claim 5 Under 35 U.S.C §112

Claims 5 stands rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Office contends that claim 1 failed to provide proper antecedent basis for claim 5. Without acquiescing to the propriety of the rejection, claims 1 and 5 have been cancelled thereby rendering the rejection moot. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

### Rejection of the Claims Under 35 U.S.C. § 102

Claims 1-14 stand rejected under 35 U.S.C. § 102 as anticipated by Ayyanagar (U.S. Patent No. 4,764,615). Claims 1-8 and 11-14 stand rejected under 35 U.S.C. § 102 as anticipated by Phillips.

Without acquiescing to the propriety of the rejection, claims 1 to 14 have been cancelled thereby rendering the rejection moot. Accordingly, Applicant respectfully requests that the rejection be withdrawn. Applicant reserves the right to pursue claims of identical and/or similar scope in one or more continuing applications.

### Rejection of the Claims Under 35 U.S.C. § 103

Claims 15-30 stand rejected under 35 U.S.C. § 103 as unpatentable in view of Ayyanagar (U.S. Patent No. 4,764,615) and Phillips (Chemist Druggist). According to the Office, in the absence of unexpected results or superior yield, it would have been obvious to one skilled in the art to use alkaline ingredients other than those disclosed in the cited Ayyanagar and Phillips references. The Office also noted that Phillips does not disclose using a particular

alkaline solution. Applicant respectfully disagrees with the rejections for the following reasons.

At the time of the invention, it was an unexpected result to achieve the high degree of conversion which results from the process of the present invention using the claimed phosphate alkaline ingredients. Specifically, one skilled in the art would have understood that using certain alkaline ingredients would result in reduced conversion of morphine component to codeine, as described at page 5, lines 6 to 8 of the present application. However, using the phosphate alkaline ingredients in the present invention, conversion was satisfactorily high, as shown in the Examples 4-7.

Additionally, by using the claimed phosphate alkaline ingredients, the present invention provides the advantageous result of simplifying the isolation procedure that removes the byproduct dimethylaniline. Specifically, as described at page 10, lines 9-24 of the instant application, by using a phosphate alkaline ingredient of the present invention, the differential solubility of the codeine salt and dimethylaniline permits the preferential precipitation of the codeine and removal of the dimethylaniline byproduct. This advantage of enhanced purification by using a phosphate of the presently claimed invention is neither disclosed nor suggested by either the Ayyanagar or Phillips disclosures.

Moreover, Phillips differs from the instant claims in that it does not disclose a specific alkaline ingredient, much less the results and advantages provided by the claimed alkaline ingredients, as detailed above. Furthermore, in view of the unexpected results and advantages provided by the presently claimed invention, the rejection under § 103 in light of the Phillips reference is improper, and applicant respectfully requests withdrawal of the rejection.

Accordingly, because 1) the yield of codeine was unexpectedly satisfactory in light of the alkaline ingredients claimed, and 2) because the presently claimed invention provides advantages over the cited art which are neither disclosed nor suggested in either reference, applicant respectfully requests that the rejections under § 103 be withdrawn.

Additionally, with respect to new claims 31-35, applicant asserts that the new claims are also allowable because the base claims upon which the new claims depend are allowable for all the reasons set forth above.

Double Patenting Rejections Under 35 U.S.C. § 101

Claims 1-14 stand rejected under 35 U.S.C. § 101 for statutory double patenting as claiming the same invention as that of claims 1-16 of U.S. Application Serial No. 10/850,015. Applicant asserts that claims 1-14 of the present application have been cancelled, and accordingly Applicant respectfully requests that the rejection be withdrawn

Summary

Applicant respectfully submits that each rejection of the Examiner to the claims of the present application has been overcome or is now inapplicable, and that claims 15-30 are now in condition for allowance. Reconsideration and allowance of these claims is respectfully requested at the earliest possible date.

Respectfully submitted,  
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